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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,668	09/30/2005	Kazuo Imose	TEI-0135	5514

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EXAMINER
JANG, CHRISTIAN YONGKYUN

ART UNIT	PAPER NUMBER
3735	

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09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,668	IMOSE, KAZUO	
	Examiner	Art Unit	
	CHRISTIAN Y. JANG	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to communications filed on April 23, 2008. The examiner acknowledges the amendments to claims 1-4 and 6-13. Claims 1-13 are pending.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (USP #6,409,675) in view of Montserrat et al. ("Effectiveness of CPAP Treatment in Daytime Function in Sleep Apnea Syndrome").

As to claim 1, Turcott teaches an examination apparatus, the apparatus comprising a biological information monitoring system (Fig. 1) with a unit for measuring and recording airflow information (410) and a unit for the analysis of the state of the sympathetic nerves based on the ECG wave (col. 15, lines 6-34), as well as an output part for displaying or printing both of a transition of respiratory airflow (410) and the enhanced state of sympathetic nerves (418). Although Turcott does not directly teach an electrode for measuring ECGs that are stuck on the skin of the subject in its preferred embodiment of an implantable device, it discloses the use of such a device

and its uses (col. 3, lines 1-39), as well as another embodiment wherein the device is not implanted, in which the use of such a system would be obvious. Turcott does not disclose the use of the device in the selection of patients for whom an oxygen therapy is effective.

Montserrat teaches the use of an oxygen therapy (commonly known as a continuous positive air pressure therapy) and its effectiveness for the purpose of treating patients with SAHS (sleep apnea/hypopnea syndrome).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to recognize the use of the device as taught by Turcott in selecting patients for whom oxygen therapy is effective in order to improve the symptoms and perceived health status of those suffering from a sleep respiratory disturbance.

As to claim 2, Turcott teaches the examination apparatus which comprises a unit for determining an electrocardiogram of the subject patient (col 7, lines 28-29), and an analysis unit for analyzing the enhanced state of sympathetic nerve based on the determined electrocardiogram wave form with a heart rate variability analytical procedure (col 7, lines 33-36).

As to claim 3, Turcott teaches the examination apparatus which comprises a sensor for detecting presence/absence or magnitude of respiratory airflow of the subject patient (Abstract), and an analysis unit (Fig. 1, 12) for analyzing synchronization of transition of the respiratory state in a Cheyne-Stokes respiratory symptom in which apnea and respiratory states are repeated with transition of abnormal enhancement of sympathetic nerve (col 7, lines 42-47).

5. Claims 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (USP #6,409,675) in view of Montserrat et al. ("Effectiveness of CPAP Treatment in Daytime Function in Sleep Apnea Syndrome") and further in view of Thomas et al. (US 2004/0144383).

As to claim 4, Turcott and Montserrat discloses the invention substantially as claimed. Turcott and Montserrat teach a therapeutic system which comprises an examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having a sleep respiratory disturbance, and/or use in ascertaining a therapeutic effect of the oxygen therapy wherein an output part for displaying or printing both of transition of respiratory airflow and transition of enhanced state of sympathetic nerve of the subject patient during sleeping is provided to the examination apparatus, with a unit for externally attached ECG electrodes and a unit for analyzing the state of the sympathetic nerves. However, Turcott and Montserrat do not disclose a supplying apparatus of an oxygen-enriched gas for respiration for the purpose of carrying out the oxygen therapy.

Thomas teaches a gas system for supplying pressurized gas (Abstract) for the purpose of providing a gas mix effective for stabilizing breathing of target patients or users. In addition, Thomas teaches that the control processor of the device may be responsive to patient state information ([0030], lines 1-5)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Turcott and Montserrat with the continuous positive air

pressure therapy system as taught by Thomas in order to enable treatment of the respiratory disturbance.

As to claim 5, Thomas teaches the therapeutic system wherein the supplying apparatus of an oxygen-enriched gas for respiration is constituted to allow flow rate of the oxygen-enriched gas for respiration to be regulatable within a predetermined range so that the flow rate becomes the amount prescribed on the basis of the result displayed or printed by the output part of the examination apparatus ([0014], lines 1-11).

As to claims 6-9, Turcott, Montserrat, and Thomas teach a method of selecting a patient containing all the limitations found in the claims. The use of the system in claims 1-5 comprises the method claimed, and is rejected accordingly for the same reasoning.

As to claims 10-13, Turcott, Montserrat, and Thomas disclose the invention substantially as claimed.

The combined teachings of Turcott, Montserrat, and Thomas do not teach selecting a patient who exhibits the results that an arterial oxygen saturation is not higher than a predetermined threshold value. However, Turcott's disclosure includes an optical sensor to determine arterial blood oxygen saturation. Oxygen toxicity, severe hyperoxia caused by breathing oxygen at elevated partial pressures, is a well known and established medical concept. Thus, it is the examiner's position that it would have been obvious for one of ordinary skill in the art to modify Turcott, Montserrat, and Thomas to exclude patients who exhibit oxygen levels above an established saturation point so that the therapy they receive do not result in hyperoxia.

Response to Arguments

5. Applicant's arguments filed April 23, 2008 have been fully considered but they are not persuasive.

6. Applicant has argued that only the vascular plethysmography and arterial oxygen saturation sensors are taught in the non-implanted monitor. The excerpt of Turcott quoted by the applicant (col. 11, lines 41-44) does not exclude every sensor to the exception of these two. It states that these two sensors, "as with most of the sensors described here" are capable of use in non-invasive external embodiments, and does not exclude any other types of sensors within such external embodiments.

7. Applicant has argued that sensors disclosed by Turcott is small and attachable to a peripheral portion of the body, whereas the monitoring system taught by the applicant is attached to the body of the subject patient. The examiner notes that the definition of the body is broad enough to encompass any part of the human body and is not limited to any specific region.

8. Applicant has argued that Turcott does not teach an output part for displaying/printing both of a transition of respiratory airflow and the state of sympathetic nerves. As stated in the above office action, Turcott clearly teaches both.

9. Applicant has argued that Turcott does not teach non-implantable electrodes. As stated above, the examiner respectfully submits that Turcott clearly teaches said type of electrodes.

10. Applicant has argued that Montserrat's disclosure of oxygen therapy (CPAP) is different from applicant's (HOT). However, applicant has not incorporated such a

limitation within the claim, merely stating the selection of a patient for whom "an oxygen therapy is effective." Examiner notes that CPAP is a well known and effective type of oxygen therapy.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

CJ
/C. Y. J./
Examiner, Art Unit 3735
08/04/08